USSN: 09/650,584 Attorney Docket No.: 22940/2

# **REMARKS**

## I. Status of the Claims

Upon entry of this amendment, claims 1-3, 5-6, 8, 11-12, 17 and 24-29 are pending in this application. Claims 7, 9, 10, 13-16 and 18-23 have been withdrawn from consideration and are cancelled without prejudice or disclaimer by this amendment. These claims are not cancelled in view of an art rejection and no estoppel is attached to their cancellation. Claim 4 has been cancelled without prejudice or disclaimer by this amendment in order to expedite prosecution of this application. Claims 1, 3 and 11 are amended herein, and claims 24-29 are newly-added by this amendment. Reconsideration and allowance of all pending claims are requested in view of the remarks below.

#### II. Information Disclosure Statements

The Office Action indicates that Information Disclosure Statements filed January 24, 2001, April 9, 2001, and May 23, 2002 have not been considered because they are not in the file. The Examiner requests that the Applicant provide them so they can be considered by the Examiner. Copies of these Information Disclosure Statements are provided herewith in paper form, with copies of the references cited therein provided on the enclosed CD-ROM. Additionally, Applicant submits herewith, a fourth Information Disclosure Statement with copies of the Information Disclosure Statement and references cited therein in paper form.

Applicant notes that because the first three Information Disclosure Statements were filed before the date of the Office Action, any new rejection of the claims based on references cited therein would appropriately be a non-final Office Action.

# III. Claim Rejections – 35 USC § 112

Claims 3, 4 and 11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant provides the following remarks.

Regarding Claim 3, the Office Action asserts that it is not clear what is the meaning of "a base curve of from about 8 to about 9 mm." Applicant notes that the term "base curve" can be found in the specification, such as page 21, line 18 and page 25, line 15. Applicant submits that the term "base curve" refers to the radius of curvature of the base, or bottom surface, of the stent.

Applicant notes that Claim 4 has been cancelled without prejudice or disclaimer in order to expedite prosecution of this application.

Regarding Claim 11, the limitation "proximal flanged" has been amended to read "cross portion", which has antecedent basis in Claim 1.

Applicant submits that, in view of the remarks above, the rejections under 35 USC § 112 are no longer appropriate and should be withdrawn.

## IV. Claim Rejections – 35 USC § 102

Claims 1-2, 5, 8, and 12 are rejected as being anticipated by U.S. Patent No. 4,521,210 to Wong (Wong). Applicant traverses this rejection.

# A. The Disclosure of Wong

Wong is directed to an eye implant for relieving glaucoma. The implant of Wong is formed to be thin, resilient, semi-rigid body having surface channels extending along its length to provide drainage passages for eye fluids. Longitudinal channels are preferably provided by corrugating the body of the device longitudinally. The Wong implant is curved along its length to match the

curvature of the interior of the sclera of the eye. The implant is preferably implanted with its tip in the peripheral angle of the anterior chamber of the eye, with its central portion extending between the sclera and the ciliary body. The opposite end extends into the suprachoroidal space, wherein eye fluids drained from the anterior chamber are absorbed. See the Abstract of Wong. In summary, Wong discloses a thin, resilient implant that is curved to <u>match</u> the curvature of the interior of the sclera of the eye to provide drainage of fluids.

# B. The Deficiency of Wong

In contrast, an embodiment of Applicant's invention is directed toward a torsion resistant stent that is provided with a cross portion for resisting torsional forces on a leg portion of the stent, thereby aiding in maintaining positioning of the stent within a tunnel formed intrasclerally in a globe of an eye. Where Wong is providing a drain, Applicant provides a device for manipulating the geometry of muscles on the eye. It is believed that use of Applicant's invention can aid influencing the geometry of the eye which may improve near distance eyesight.

Applicant submits that Claim 1 is not anticipated by Wong for at least two reasons. First, Wong does not teach providing an arcuate portion having "a curvature greater than a radius of curvature of the globe in the area of the tunnel" of the eye, as recited in Claim 1. Instead, Wong discloses an implant matching the curvature of the sclera of the eye. See the Abstract of Wong. Column 2, lines 24-25, of Wong describe an implant "curved to follow the configuration of the limbal region of the eye." Therefore, Wong does not teach a curvature greater than a radius of curvature of the globe in the area of the tunnel. For at least this reason, Wong is insufficient to sustain a rejection of 35 USC § 102 of Claim 1.

USSN: 09/650,584 Attorney Docket No.: 22940/2

Secondly, Applicant notes that Claim 1 is directed to a scleral-tensioning stent. Applicant notes that Wong does not disclose such a stent, and is therefore also insufficient to sustain the rejection under 35 USC § 102 of Claim 1.

The Office Action asserts that functional language in the claims have been considered but not given much patentable weight because they indicate intended use and do not provide further structural limitation. Applicant submits that the recitation of the curvature of the arcuate portion is specific structural language that must therefore be given patentable weight. Secondly, the recitation of a scleral-tensioning stent requires structure capable of tensioning of the sclera. There is therefore, necessarily, a structure associated with a scleral-tensioning stent and this language can not be dismissed as simply intended use. Applicant submits that Wong does not teach either an arcuate portion as recited in the claims nor a scleral-tensioning stent and is therefore incapable of sustaining a rejection of Claim 1.

Applicant asserts that Claims 2-4, 5-6, 8, and 11-12 are patentable in part by way of their dependency from Claim 1.

## V. Claim Rejections – 35 USC § 103

Claims 6 and 17 are rejected as being unpatentable over U.S. Patent No. 4,521,210 to Wong. Applicant traverses this rejection.

#### A. Claim 6

Applicant asserts that Claim 6 is patentable in part by way of its dependency from Claim 1.

Applicant references the discussion above regarding the patentability of Claim 1 over Wong, and asserts that Wong is insufficient to teach or suggest all the limitations of Claim 1, from which Claim

USSN: 09/650,584 Attorney Docket No.: 22940/2

6 depends. For example, Wong does not teach or suggest providing an arcuate portion having "a curvature greater than a radius of curvature of the globe in the area of the tunnel" of the eye, as recited in Claim 1. Also, Wong does not disclose or suggest a scleral-tensioning stent, and is therefore also insufficient to sustain a rejection of Claim 1 or 6. In view of the above, Applicant asserts that the rejection of Claim 6 under 35 USC § 103 should be withdrawn.

#### A. Claim 17

With reference to Claim 17, Applicant submits that Wong is insufficient to sustain the rejection under 35 USC § 103. Specifically, Claim 17 recites a torsion resistant stent comprising at least about four torsion resistant scleral-tensioning stents positioned about equidistant about the sclera. Wong does not render such a configuration obvious, in part because Wong does not teach or suggest torsion resistant sclera-tensioning stents or having at least about four of such stents about equidistant about the sclera. The drain of Wong is not a sclera-tensioning stent.

The Office Action asserts that functional language in the claims have been considered but not given much patentable weight because they indicate intended use of the device and do not provide any further structural imitation of the device. Applicant asserts that the language of Claim 17 noted above is not functional language directed toward intended use. Instead, this language recites specific structure, such as torsion resistant sclera-tensioning stents, and how such stents are located in relation to each other. The recitation of position of structures relative to each other is structural language that must be given patentable weight.

USSN: 09/650,584 Attorney Docket No.: 22940/2

VI. Newly-Added Claims

Claims 24-29 are newly added by this amendment and drawn to Group I and at least species

1. Applicant submits that Claim 24 is patentable over Wong in part because Wong does not teach or

suggest a flange that is integrally formed with and at a first end of an elongated portion of a scleral-

tensioning stent, as recited in Claim 24. Applicant asserts that Claims 25-29 are patentable in part

by way of their dependency from Claim 24. In view of the cancellation of the claims withdrawn

from consideration, claims 7, 9, 10, 13-16 and 18-23, no excess claim fee is due.

CONCLUSION

In view of the remarks set forth above, it is respectfully submitted that this application is in

condition for allowance. Accordingly, allowance is requested. If the Examiner feels that a further

telephone conference would expedite allowance/issuance of this case, or resolve any remaining

issues, the Examiner is invited to contact the undersigned at (617) 856-8382.

Respectfully submitted,

Date: September 1, 2004

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